MONTANA CANCER CONTROL PROGRAMS
MONTANA DEPARTMENT OF PUBLIC HEALTH AND HUMAN SERVICES

POLICY AND PROCEDURE FOR ACCESS TO DE-IDENTIFIED DATA FOR RESEARCH PURPOSES FROM THE MONTANA CENTRAL TUMOR REGISTRY

The Montana Central Tumor Registry of the Department of Public Health and Human Services collects data based on the reporting of cancer cases under Montana statutes MCA-2007-50-15-703 and 50-15-705. These data are confidential and access to them is strictly regulated by Montana statutes MCA-2007-50-15-704 and 50-16-603. Release of any data contained in the Montana Central Tumor Registry is subject to additional restrictions regarding medical information imposed by the Health Insurance Portability and Accountability Act (HIPAA) and all other applicable federal laws.

This policy establishes guidelines and procedures to allow use of the data for public health and epidemiologic research while protecting the integrity and confidentiality of the Montana Central Tumor Registry in compliance with state statutes and federal laws. To do this, the Montana Central Tumor Registry will consider requests to enter into Data Use Agreements which protect the privacy of the information provided to institutions or investigators.

The Montana Central Tumor Registry may, at its discretion, provide de-identified cancer data to institutions or investigators conducting public health or epidemiologic research. Data will also be provided to individuals or agencies requiring the information to fulfill legal mandates, when data are needed to conduct the agency's official duties; or to individuals or agencies conducting research projects already authorized by the Montana Department of Public Health and Human Services.

Except under extraordinary circumstances (which include at the minimum explicit, signed informed consent from all individual patients concerned), no identified or re-identifiable data will be released. **There is no provision under Montana statute for the waiver of informed consent.** Potential access to identified data is the subject of a separate policy.

Under no circumstances shall any information be given to any organization or individual in order to solicit sale of a product, offer any service for compensation, distribute partisan literature, or use for any other political or commercial purpose.

Definition of Identifying Information:

All identifying information is confidential and will not be released. Identifying information includes patient name, address, birth date, social security number, **or any other information which, alone or in combination with other data, could be used to determine with reasonable accuracy the identity of an individual**.

The Montana Central Tumor Registry's Data Use Review Committee will determine the extent to which specific data elements or combinations of data elements may render individuals potentially re-identifiable in an otherwise de-identified data set.

Identifying information also includes the names and addresses of reporting institutions and health care providers.

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The Montana Central Tumor Registry's Data Use Review Committee:

The Data Use Review Committee is made up of the Manager of the Cancer Surveillance and Epidemiology Program, the Data Use Officer of the Montana Central Tumor Registry, the State Medical Officer, and a member external to DPHHS. The external member will be selected by the other committee members on the basis of knowledge of research design and familiarity with human subjects research. The external member will ordinarily serve for 12 months at a time and may be invited to continue serving for an unlimited number of terms.

The committee will review each request, make a recommendation for approval or disapproval, and forward the request to the Chief of the Chronic Disease Prevention and Health Promotion Bureau for review, and then to the Administrator of the Public Health and Safety Division for final disposition. The Committee, Bureau Chief, or Division Administrator may refer the request to the Legal Counsel of the Montana Department of Public Health and Human Services for advice before a final decision is made.

Restrictions of Data Use:

Data sets released by the Montana Central Tumor Registry may not be used for attempted linkage to any other data set(s).

No efforts may be made to re-identify any individuals contained in data sets released by the Montana Central Tumor Registry.

No follow-up or contact with patients may be attempted based on information contained in data sets released by the Montana Central Tumor Registry.

Procedure to Request a De-Identified Data Set:

An institution or investigator must submit a copy of the research protocol and a signed Montana Central Tumor Registry Data Use Request by mail, e-mail, or fax. E-mailed requests may use a scanned signature.

The Montana Central Tumor Registry's Data Use Review Committee will review the request. If the information provided is not sufficient to make a decision about project approval, the Review Committee will request clarification from the applicant.

The Data Use Review Committee is charged with balancing the need to protect individual privacy with the desire to have data from the Montana Central Tumor Registry used to further public health and epidemiologic research. To this end, applicants for data set are asked to provide a description of the research protocol and anticipated analysis, to enable the Committee to make an informed decision.

A written explanation will be provided for provisional or final disapproval of a request. If disapproval is provisional, a revised Data Use Request with resolution of the reasons for

provisional disapproval will be considered. If disapproval is final, a revised submission will not be considered.

The applicant of an approved request will be required to pay a $50.00 fee for the preparation of a Data Use Agreement. Two original copies of the Agreement must be signed by the Principal Investigator and a senior official at the investigator's institution such as the Dean of Research or Vice President for Research, if applicable, and returned to the Montana Central Tumor Registry, where they will be signed by the Division Administrator and the Chair of the Data Use Review Committee. A signed copy will be returned to the applicant when the data set is released.

Institutional Review Board / Human Subjects Protection Committee Approval:

All applicants requesting a data set for research purposes[§] must have a final IRB or Human Subjects Protection Committee approval from an entity recognized by the Office for Human Research Protections of the US Department of Health and Human Services. All uses of Montana Central Tumor Registry data constitute research with human subjects. No use of Montana Central Tumor Registry data is eligible for exemption from IRB, regardless of the exemption status of the project as a whole. The Montana Central Tumor Registry's Data Use Review Committee will consider, but does not commit to accept, a request that has passed an expedited IRB review and approval process.

There is no provision under Montana statute for the waiver of informed consent for the release of individually identifiable data under any circumstances, regardless of the determination of an IRB that a waiver may be acceptable for the project as a whole.

In view of the time required for the IRB process, a request may be submitted to the Montana Central Tumor Registry's Data Use Review Committee before IRB approval is final, but the process should be well underway. Provisional approval for a Data Use Agreement may be granted before the IRB process is complete but a data set will not be released until final IRB approval is documented.

Duration of a Data Use Agreement:

A Data Use Agreement will ordinarily be for one year (with potential for renewal), but may not exceed the effective dates of the corresponding IRB approval. If necessary, the applicant must obtain an IRB extension before a Data Use Agreement will be renewed.

It will be the responsibility of the applicant to be sure that IRB extensions and requests for renewal of the Data Use Agreement are current. Lapse of either or both will result in the cancellation of a Data Use Agreement.

[§] The Office for Human Research Protection's definition of research is "a systematic investigation designed to develop or contribute to generalizable knowledge."

Graduate Student Projects:

Graduate students and their academic advisors are encouraged to contact the Manager of the Cancer Surveillance and Epidemiology Program to discuss the possibility of using Montana Central Tumor Registry data sets for professional papers, theses, or dissertations. A formal Data Use Request should not be submitted unless it is agreed that the proposed student project is appropriate and feasible.

A graduate student must complete a Data Use Request plus a supplemental section documenting approval of the professional paper, thesis, or dissertation topic and research plan by a graduate committee or preceptor. The chair of the graduate committee or preceptor must co-sign the request and Data Use Agreement, if granted, with the student.

Because of the need for IRB approvals, Data Use Review Committee action, and the time required for Montana Central Tumor Registry staff to prepare data sets, requests for data sets for other student activities (e.g., term papers, class projects, and most undergraduate uses) will not be considered. Data sets will not be released for instructional purposes.

Multiple Research Projects:

Institutions or investigators using data from the Montana Central Tumor Registry may use it only for the project for which approval was granted. The data provided for one project may not be used for a second or follow-up project without additional written agreements.

Data Use Agreement:

All Data Use Agreements with the Montana Central Tumor Registry are subject to unilateral cancellation at any time at the discretion of the Montana Central Tumor Registry, the Data Use Review Committee, or the Montana Department of Public Health and Human Services.

Each Data Use Agreement will be individually drafted to cover all reasonably anticipated circumstances for each release of the data. All investigators (excluding direct subordinates of the primary investigator) and all institutions who need access to the data must sign a Data Use Agreement. **Contractual arrangements or other agreements among investigators or institutions may not be used to share Montana Central Tumor Registry data with third parties.**

Each Data Use Agreement will contain, at the minimum, the following elements.

1. Identification of Institution
2. Identification of Primary Investigator
3. Identification of staff supervised by Primary Investigator who will have access to the data in the course of their routine duties.
4. Commitment not to release the data to third parties.
5. Commitment not to attempt linkage with other data sets.
6. Commitment not to attempt to re-identify patients, institutions, or care givers contained in the data set.
7. Commitment not to attempt follow-up or contact of individuals contained in the data set.
8. Specification of minimum cell size to be suppressed in any reports based on the data set.
9. Agreement to destroy the data set at the end of the project.
10. Commitment to use the data only for the approved project.
11. The effective dates of the Agreement. In general this will be one year, subject to application for renewal.
12. Description of physical and electronic security measures to be used to protect the data.
13. A summary statement listing all uses of the data and a complete copy of the protocol as an Appendix.
14. Statement addressing penalties for violation of the Data Use Agreement. At the minimum, violation will result in immediate cancellation of the Data Use Agreement. The Montana Department of Public Health and Human Services reserves the right to pursue legal action at its discretion.

Fees:

There will be no fee for the consideration of a Request for Data.

There will be a $50.00 fee for the preparation of a Data Use Agreement.

Instructions for payment will be provided when a Data Use Request is approved.

A waiver of this fee will be granted to graduate students on request if they do not have a grant or a faculty or institutional sponsor to pay the fee.